

SEP 29 2004

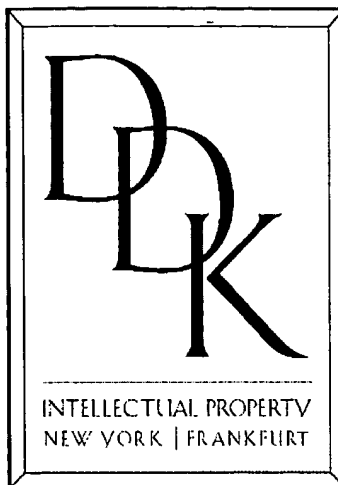
IFW

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September 22, 2004

**VIA PRIORITY MAIL**

Alan Koller, Ph.D., Esq.  
Sr. Assistant General Counsel  
Purdue Pharma L.P.  
One Stamford Forum  
Stamford, CT 06901

Re: U.S. Patent Application No. 10/692,662  
Entitled: **ANALOGS AND PRODRUGS OF BUPRENORPHINE**  
Euro-Celtique, S.A.  
Your Ref. No.: PT1002  
Our Ref. No.: 208.1007US

Dear Alan:

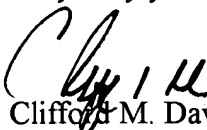
We have now received an Office Action for the above-referenced patent application, a copy of which along with related papers are enclosed for your review.

A response to the Office Action is due **December 9, 2004**, although extensions of time are obtainable if necessary.

In the Office Action, the Examiner rejected claims 1-8, 11-16 under 35 U.S.C. 102(b) as being anticipated by compounds in Figure 1 page 264 of the Imoto et al. cited in the Examiner's PTO-892 Form. A copy of this reference is enclosed, as well. Claims 9 and 10 were allowed the Examiner stating that "the side-chain substituents on the fused benzene ring are novel and unobvious".

Absent your instructions to the contrary, we shall prepare a draft response for your review and consideration prior to the due date. On the other hand, if you have any comments or suggestions concerning this Office Action, we look forward to receiving the same.

Very truly yours,

  
Clifford M. Davidson

CMD:ie  
Enclosure

cc: Robert J. Paradiso, Esq.



UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/692,662      | 10/24/2003  | F. Peter Boer        | 208.1007US          | 9936             |

7590

09/09/2004

DAVIDSON, DAVIDSON & KAPPEL, LLC  
14th Floor  
485 Seventh Avenue  
New York, NY 10018

EXAMINER

TRINH, BA K

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 09/09/2004

RECEIVED  
SEP 13 2004

Please find below and/or attached an Office communication concerning this application or proceeding.

DAVIDSON, DAVIDSON & KAPPEL

Excel 9-14-04  
IPM 9-14-04

10-3-05 OFFICE ACTION Response due  
(Deadline Date)  
12-9-04 OFFICE ACTION Response due  
(3 month date)  
11-9-04 Reminder  
10-9-04 send reporting letter  
CMD/RJP/EP

# Office Action Summary

Application No.

10/692,662

Applicant(s)

BOER ET AL.

Examiner

Ba K. Trinh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10/24/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 and 10 is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 07/12/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1-16 are pending.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by compounds in Figure 1 page 264 of Imoto et al.

Claims 9 and 10 are allowable since the side-chain substituents on the fused benzene ring are novel and unobvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ba K. Trinh whose telephone number is (571) 272-0695. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

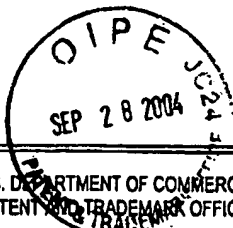
Art Unit: 1625

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ba K. Trinh  
Primary Examiner  
Art Unit 1625

TRINH/BKT  
September 07, 2004



|   |    |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
|---|----|--|---|----------------------------------|---|---------------------------|---|---|------------|-------------------------------|-------|----------|-------------------------------|----|
| FORM PTO-1449<br>(REV. 7-80)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE |   | ATTY. DOCKET NO.:<br>208.1007us  |   | SERIAL NO.:<br>10/692,662 |   |   |            |                               |       |          |                               |    |
| LIST OF PRIOR ART CITED BY APPLICANT<br><br>(Use several sheets if necessary)   |    |  |   | APPLICANT(S):<br>Boer et al.     |   |                           |   |   |            |                               |       |          |                               |    |
|   |    |  |   | FILING DATE:<br>October 24, 2003 |   | GROUP:<br>1642-1625       |   |   |            |                               |       |          |                               |    |
| U.S. PATENT DOCUMENTS   |    |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
| *EXAMINER<br>INITIAL  |    | DOCUMENT NUMBER  |   |                                  |   |                           |   |   | DATE       | NAME                          | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |    |
| BT  | AA | 4  | 5 | 8                                | 8 | 5                         | 8 | 0 | 05/13/1986 | Gale, et al.                  | 424   | 21       |                               |    |
| BT  | AB | 4  | 8 | 0                                | 6 | 3                         | 4 | 1 | 02/21/1989 | Chien, et al.                 | 424   | 448      |                               |    |
| BT  | AC | 5  | 0 | 2                                | 6 | 5                         | 5 | 6 | 06/26/1991 | Drust, et al.                 | 424   | 449      |                               |    |
| BT  | AD | 5  | 0 | 6                                | 9 | 9                         | 0 | 9 | 12/03/1991 | Sharma, et al.                | 424   | 449      |                               |    |
| BT  | AE | 5  | 2 | 2                                | 5 | 1                         | 9 | 9 | 07/06/1993 | Hidaka, et al.                | 424   | 443      |                               |    |
| BT  | AF | 5  | 2 | 4                                | 0 | 7                         | 1 | 1 | 08/31/1993 | Hille, et al.                 | 424   | 448      |                               |    |
| BT  | AG | 5  | 9 | 0                                | 8 | 8                         | 4 | 6 | 06/01/1999 | Bungaard et al.               | 514   | 282      |                               |    |
| BT  | AH | 5  | 9 | 6                                | 8 | 5                         | 4 | 7 | 10/19/1999 | Reder et al.                  | 424   | 449      |                               |    |
| BT  | AI | 6  | 2 | 3                                | 1 | 8                         | 6 | 6 | 05/15/2001 | Reder et al.                  | 424   | 449      |                               |    |
| BT  | AJ | 6  | 3 | 4                                | 4 | 2                         | 1 | 2 | 02/05/2002 | Reder et al.                  | 424   | 449      |                               |    |
| FOREIGN PATENT DOCUMENTS  |    |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
|   |    | DOCUMENT NUMBER  |   |                                  |   |                           |   |   | DATE       | COUNTRY                       | CLASS | SUBCLASS | TRANSLATION                   |    |
|   |    |  |   |                                  |   |                           |   |   |            |                               |       |          | YES                           | NO |
| BT  | AK | 9  | 6 | 1                                | 9 | 9                         | 7 | 5 | 12/24/1994 | WO                            | A61K  | 9/70     | abstract                      |    |
|   | AL |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |    |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
|   | AM |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
|   | AN |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
|   | AO |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
|   | AP |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
|   | AQ |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
|   | AR |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
|   | AS |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |
| EXAMINER<br><br>[Signature]   |    |  |   |                                  |   |                           |   |   |            | DATE CONSIDERED<br><br>9/2004 |       |          |                               |    |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |    |  |   |                                  |   |                           |   |   |            |                               |       |          |                               |    |

**Notice of References Cited**

Application/Control No.

10/692,662

Applicant(s)/Patent Under  
Reexamination  
BOER ET AL.

Examiner

Ba K. Trinh

Art Unit

1625

Page 1 of 1

**U.S. PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name | Classification |
|---|---|--|-----------------|------|----------------|
|   | A | US-  |                 |      |                |
|   | B | US-  |                 |      |                |
|   | C | US-  |                 |      |                |
|   | D | US-  |                 |      |                |
|   | E | US-  |                 |      |                |
|   | F | US-  |                 |      |                |
|   | G | US-  |                 |      |                |
|   | H | US-  |                 |      |                |
|   | I | US-  |                 |      |                |
|   | J | US-  |                 |      |                |
|   | K | US-  |                 |      |                |
|   | L | US-  |                 |      |                |
|   | M | US-  |                 |      |                |

**FOREIGN PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name | Classification |
|---|---|--|-----------------|---------|------|----------------|
|   | N |  |                 |         |      |                |
|   | O |  |                 |         |      |                |
|   | P |  |                 |         |      |                |
|   | Q |  |                 |         |      |                |
|   | R |  |                 |         |      |                |
|   | S |  |                 |         |      |                |
|   | T |  |                 |         |      |                |

**NON-PATENT DOCUMENTS**

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|---|
|   | U | Imoto et al., Biol. Pharm. Bull., Vol. 19 (2), pages 263-267, 1996.                       |
|   | V |   |
|   | W |   |
|   | X |   |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.